

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

KATO, et al.

Serial No.: 10/506,335

Group Art Unit: 1619

Filed: September 2, 2004

Examiner: GULLEDGE, B.R.

For: Whitening Cosmetic Composition

DECLARATION UNDER 37 CFR §1.132

I, Eiko KATO, hereby declare and state that:

I am a citizen of Japan, residing at Chuo-ku, Chiba-shi, Chiba.

2. I work in the section of Show Denko Co., Ltd., in which research and development related to the present invention were performed. I am fully familiar with the subject matter of the present application as well as the references relied upon by the Examiner in the prosecution of this application.

3. I obtained a bachelor's degree from Japan Woman's University, department of chemical and biological Sciences, in March 1989, where I studied plant physiology.

4. I am currently employed by Show Denko Co., Ltd., and began working for Showa Denko Co., Ltd., in April 1989, where I have engaged in research and development relating to functional chemicals.

5. I have conducted the tests described below.

#### **Object of Test**

To determine the lower limit of the effective amount of an active ingredient in the whitening cosmetic composition of the present invention.

#### **Experiments and Evaluation**

Seven kinds of lotions as shown in the table below were prepared. Each of the lotions was evaluated for prevention of pigmentation as in Example 5 of the original specification of the present invention.

Specifically, hair on the entire surface of the back of each of 8 male Wistar-Kyoto guinea pigs (WM, SPF) was cut by means of electric hair clippers (0.05 mm blade), was subsequently shaved by means of an electric shaver, followed by covering with an adhesive stretch bandage (SILKYTEX, covered the outside thereof with an aluminum foil) wherein 4 holes of 1.5 cm X 1.5 cm had been formed. Subsequently, the animal was held by a retainer, followed by exposure of UV rays having medium wavelength (UVB) of 750 mJ/cm<sup>2</sup> to each part from a distance of approximately 10 cm by means of a UV exposure apparatus (Shinano Co., Ltd.,

Toshiba FL40S/E30 model fluorescent lamp, equipped with six SE lamps).

From 4 days after the exposure to 28 days, each product of the Lotions a. to g. in an amount of 0.05 ml was successively applied to 8 holes twice a day, that is in the morning and in the evening.

Twenty-eight days after the exposure, the strength of pigmentation was evaluated by evaluation points according to the evaluation criteria described below. The effects of preventing pigmentation were evaluated by the average value obtained from the evaluation points (10 data), and are shown in the following table.

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	Lotion ID.	a	b	c	d	e	f	g
Tocopherol derivatives	dl- $\alpha$ -tocopherol dimethylglycine ester hydrochloride	0.5	0.3	0.1	-	-	-	-
	dl- $\gamma$ -tocopherol dimethylglycine ester hydrochloride	-	-	-	0.5	0.3	0.1	-
Ethanol		40.0	40.0	40.0	40.0	40.0	40.0	40.0
Propylene glycol		40.0	40.0	40.0	40.0	40.0	40.0	40.0
Methyl p-hydroxybenzoate		0.2	0.2	0.2	0.2	0.2	0.2	0.2
Purified water		balance	balance	balance	balance	balance	balance	balance
Evaluation (average)		2.2	2.4	3.0	2.0	2.2	3.0	3.7

## Evaluation Criteria

No pigmentation is observed      evaluation point 0  
 Very slight pigmentation is observed      evaluation point 1  
 Slight pigmentation is observed      evaluation point 2  
 Fair degree of pigmentation is observed      evaluation point 3  
 Strong pigmentation is observed      evaluation point 4

**Conclusion**

As shown in Table, Lotions c. and f., which contain 0.1 wt% of either dl- $\alpha$ -tocopherol dimethylglycine ester hydrochloride or dl- $\gamma$ -tocopherol dimethylglycine ester hydrochloride have evaluation points (average) between 3.0 and 3.7; while Lotions a., b, d. and e., which contain 0.3 wt% or more of either dl- $\alpha$ -tocopherol dimethylglycine ester hydrochloride or dl- $\gamma$ -tocopherol dimethylglycine ester hydrochloride, have evaluation points (average) between 2.0 and 2.4. Lotion g., which contain neither dl- $\alpha$ -tocopherol dimethylglycine ester hydrochloride nor dl- $\gamma$ -tocopherol dimethylglycine ester hydrochloride, has evaluation point (average) of 3.7.

Based on these comparisons, it has become clear that dl- $\alpha$ -tocopherol dimethylglycine ester hydrochloride and dl- $\gamma$ -tocopherol dimethylglycine ester hydrochloride in an amount of 0.3 wt% or more has effects of preventing pigmentation superior to that of other compounds.

6. I understand fully the content of this declaration.

7. I, Eiko KATO, the undersigned declarant declares further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001, of Title 18 of the United States Code, and that such willful false

statements may jeopardize the validity of the application  
or any patent issuing thereon.

Date: Mar/10/2010

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Eiko Kato